Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices

DRAFT DOCUMENT

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Ear, Nose, Throat and Radiological Devices
Office of Device Evaluation

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Comments and suggestions regarding this draft document should be submitted within 30 days of the above release date to Robert A. Phillips, Ph.D., HFZ-470, 9200 Corporate Blvd., Rockville, MD 20850. Comments and suggestions received after this date may not be acted upon by the Agency until the document is next revised or updated. For questions regarding this draft document contact Robert J. Doyle at (301) 594-1212.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

I. Table of Contents

II. Scope: This guidance applies to a new category of medical devices, Solid State X-ray Imagers (SSXI) that convert input x-rays directly to electrical signals. The signals can in turn, with or without processing, be displayed for use in medical diagnosis. These devices are intended to replace conventional x-ray film/screen systems, and image intensifier based fluoroscopic and image recording systems. SSXI's indicated for mammography do not fall within the scope of this guidance.

III. Purpose: As solid state imaging technology continues to progress, solid state x-ray imaging devices will assume an ever increasing role in medical x-ray systems. This evolution will result in a significant number of premarket (510(k)) submissions based on this new technology. This document is intended to provide guidance as to the type of data needed by the Center for Devices and Radiological Health (CDRH) to establish the substantial equivalence of an SSXI to a previously cleared conventional radiographic film/screen system, fluoroscopic image intensified imaging system, or SSXI.

IV: Description: The devices covered by this guidance are solid state arrays of transducers (typically a thin flat rectangular panel) that intercept x-ray photons, and through one of several possible processes convert the photon energy into an electrical signal that is used to create a visible image. The two basic methods currently available to perform the x-ray conversion are:

1. A two stage process, where the input x-ray photons are absorbed by a scintillator (such as cesium iodide). The scintillator emits visible spectrum photons illuminating a matrix of scanned photodetectors that generate a modulated electrical signal.

2. A single stage process where the input x-ray photons are absorbed directly by a scanned detector matrix (such as amorphous silicon) that generates a modulated electrical signal.

After the electrical signal is generated, it can be processed to enhance the visibility of the viewed image or a portion thereof. It can also be transmitted to remote viewing sites, and/or it can be stored electronically for later viewing. The signals can also be input to a camera (e.g. laser scanner) to make hard copy positive or negative transparencies of the images.

V. Regulatory Requirements: Prior to marketing, new x-ray imaging devices must conform to the Radiation Control for Health and Safety Act of 1968 (RCHSA) and the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act of 1976.

These devices, being a part of a diagnostic x-ray system, must also conform to the Performance Standards for Ionizing Radiation Emitting Products. Specifically they must meet applicable sections of 21CFR1020.30 Diagnostic x-ray systems and their major components, 1020.31 Radiographic equipment, or 1020.32 Fluoroscopic equipment.

Under Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act of 1976, a device may be cleared for marketing via a 510(k) premarket notification. To do so, the device must be shown to be substantially equivalent to a legally marketed predicate device. Predicate devices for SSXI's must be preamendment or cleared devices that have the same or similar intended use(s) as the device being submitted for clearance. The fact that such a predicate may itself be exempt from 510(k) requirements does not exempt the SSXI's from this requirement (ref. 21 CFR 892.9 (b)). SSXI's operate using a different fundamental

scientific technology than film or image intensifiers and, therefore, are not exempt from the requirements of 510(k).

Product Code "90 MQB" has been established for SSXI's and they are currently considered Class II when they are found equivalent to radiographic film or an image intensifier tube.

Sections VI and VII that follow describe the nonclinical and clinical data necessary to establish the substantial equivalence of the new device to the identified predicate device(s).

VI. Nonclinical Considerations In addition to the General Information required for all medical devices submitted for 510(k) clearance (Ref.: 21 CFR 807.87) the following nonclinical information specific to SSXI's should also be included. This information will assist in determining the equivalence to the predicate device(s) identified by the sponsor.

Unless stated otherwise herein or by the manufacturer, all characteristics and measurements reported are assumed to be taken while the device is functioning at room temperature.

A. For Fluoroscopic Applications

1. Physical Characteristics

a. Overall Dimensions, include length, width, thickness and any shape characteristics that are unique to the device.

b. Sensor Element Dimensions and Spacings including the fill factor, and any features added to compensate for input photon loss resulting from inactive interelementspacing.
Include total horizontal and vertical element count.

c. Structure Crossection showing the position and relative thickness of the elemental layers that constitute the device. This description should include both active and passive layers and describe the function of each.

d. Device Layout showing a representative group of elements and how they are interconnected. This description should also show the interconnection paths and electrodes that carry signals from a row of elements to the output.

e. Schematic Diagram of the elemental signal storage scheme and the overall "scanning" and readout mechanism.

f. Input Electrical Power with tolerance limits and effects of power noise on the operation of the device.

2. Operational Functions

a. Method(s) of Exposure, rates of response (frames per second): Describe a typical fluoroscopic sequence from turn-on of the device to presentation of the image to the user.

b. X-ray Absorber(s), material description: Describe the primary x-ray detection material and its x-ray detection properties as a function of photon energy (keV) or wavelength (mm); including any nonlinear response characteristics.

c. Energy Conversion Mechanisms utilized (e.g. x-ray to light to electrical signal): Describe all the processes in the device that involve energy conversion (e.g. x-ray to visible); include efficiencies and efficiency changes as a function of wavelength for each.

d. Storage Mechanisms, techniques used to integrate signals between scans: Describe the mechanism(s) used to store signals between readout commutations.

e. Readout Mechanisms, techniques used to commutate detector elements: Describe the means used to sequentially read-out the signal from successive elements. Include maximum rates and means for establishing synchronization with display devices.

f. Output Data, direct access to output signals: Describe the means provided for the user and/or evaluator to directly access the output data from the device. Indicate what communications standard (e.g. DICOM) is used to format the data for downloading and analysis.

3. Functional Characteristics

a. Output Format of the video signal, standards and sample waveform: Provide sketch or photograph of horizontal scan line and vertical field signals noting key elements of signal.

b. DQE versus Spatial Frequency: Provide a plot or table of Detective Quantum Efficiency (DQE) versus frequency up to the Nyquist limit of the device. Indicate the input exposure used, and the effects of exposure on DQE.

c. Quantum Limited Performance: Provide data showing that the device operates in a quantum limited mode at the frame rates and exposure levels specified for its use. If not quantum limited, indicate why, and what the quantum efficiency is.

d. MTF or CTF of the device: Provide a plot of the Modulation or Contrast Transfer function of the device. Indicate the device settings and input dose level required to obtain the measurement. If the transfer characteristic varies with any other function indicate how and provide the maximum and minimum transfer functions that the device provides when used with typical clinical exposures.

e. Aliasing: Quantify the effects aliasing has on the DQE and Modulation Transfer Function (MTF) of the device. If aliasing is evidenced from the pre-sampled MTF, quantitatively describe how it affects the resulting image. If there are no aliasing effects from the device indicate why.

f. Transfer Characteristic (Dynamic Range): Provide a plot of the output signal level as a function of input dose level for a specified x-ray spectrum. The spectrum may be

defined in terms of kVp and beam filtration. Plot so that any nonlinearities are clearly shown.

g. Lag or residual signal level from prior exposures short term and long term: Describe, quantitatively where possible, any device characteristics (often due to electron or hole trapping) that cause the device to include in the output, signal components attributable to one or more prior exposures. Indicate the relative amplitude and decay characteristics of such signals.

h. Spectral Sensitivity variations across the normal fluoroscopic exposure range: Provide a plot of the spectral sensitivity of the device from 30 to 130 kVp in 10 kVp steps. Indicate the beam hardness (half value layer thickness) used.

j. Any means provided to expose and/or readout subsections (partial areas) of the full SSXID: Describe, if this is a characteristic of the device, how it can be under scanned so that only a portion of the total detector matrix is utilized.

k. Alignment and Collimation: Describe how x-ray beam alignment and collimation to the "active" area of the device will be achieved to meet the requirements of 21CFR1020.32.

l. Defect Characteristics: Describe the allowable types and quantity of defects, and any methods of compensation or blanking that are utilized to compensate for allowable maximum output, minimum output or otherwise inoperative cells.

4. Exposure Characteristics

a. Dose Requirements and any reciprocity changes: Provide quantitative measurements of the device input dose required to generate an image (frame) equivalent to those provided by a cleared predicate device using the same dose. Also indicate any changes in this characteristic that will occur with time and/or cumulative radiation exposure.

b. Stability of device characteristics with time (total integrated exposure): In addition to exposure requirement changes, indicate any other characteristics of the device that change with time and/or total integrated exposure.

c. Uniformity of device characteristics (large and small area): Describe any nonuniformity characteristics of the device that may cause large or small area changes such as shading.

d. Frame Rate: Indicate the maximum number of images that can be generated per unit time and any characteristic changes that occur at different frame rates. If the frame rate limit is a function of another characteristic(s) [outside the SSXI] indicate which ones and show how that characteristic impacts the frame rate.

5. Safety Features

a. Indicate what means are provided to ensure the SSXI is ready to accept and process the signal resulting from an x-ray input before an exposure is permitted.

b. Describe the means provided to couple with the beam limiting device to ensure that the entire exposed area is being detected and is capable of being read-out.

c. Verify with measured data that the patient entrance exposure limits specified in 21CFR1020.32 can be met using this device.

6. Test Results

a. Provide samples of test pattern images that show the ability of the device to provide images equivalent to those of a predicate device(s). Each image should have with it the x-ray factors used and the set-up parameters of the device. The test patterns must be clearly identified and all characteristics indicated (e.g. lp/mm for each bar group). The geometry of the test set-up must be indicated as well as the focal spot size of the x-ray source. The images may be on film recorded from the output, or VHS video tape. If processing is used to demonstrate capabilities such as dynamic range windowing, the details of the processing should be provided.

b. Provide sample measurements of the characteristics described in 3 and 4 above.

B. For Radiographic Applications

1. Physical Characteristics

a. Overall Dimensions, include length, width, thickness and any shape characteristics that are unique to the device.

b. Sensor Element Dimensions and Spacings including the fill factor, and any features added to compensate for input photon loss resulting from inactive interelement spacing. Include total horizontal and vertical element count.

c. Structure Crossection showing the position and relative thickness of the elemental layers that constitute the device. This description should include both active and passive layers and describe the function of each.

d. Device Layout showing a representative group of elements and how they are interconnected. This description should also show the interconnection paths and electrodes that carry signals from a row of elements to the output.

e. Schematic Diagram of the elemental signal storage scheme and the overall "scanning" and readout mechanism.

f. Input Electrical Power with tolerance limits and effects of power noise on the operation of the device.

2. Operational Functions

a. Method(s) of Exposure: Describe a typical exposure sequence from turn-on of the device to presentation of the image to the user.

b. X-ray Absorber(s), material description: Describe the primary x-ray detection material and its x-ray detection properties as a function of photon energy (keV) or wavelength (mm); including any nonlinear response characteristics.

c. Energy Conversion Mechanisms utilized (e.g. x-ray to light to electrical signal): Describe all the processes in the device that involve energy conversion (e.g. x-ray to visible); include efficiencies and efficiency changes as a function of wavelength for each.

d. Storage Mechanisms, techniques used to integrate x-ray input before readout: Describe the mechanisms used to store the integrated signal prior to readout.

e. Readout Mechanisms (external or internal) techniques used to readout the device elements: Describe the means used to sequentially read-out the signal from successive elements. Include the maximum rates for doing so.

f. Output Data, direct access to output signals: Describe the means provided for the user and/or evaluator to directly access the output data from the device. Indicate what communications standard (e.g. DICOM) is used to format the data for downloading and analysis.

3. Functional Characteristics

a. DQE versus Spatial Frequency: Provide a plot or table of Detective Quantum Efficiency (DQE) versus frequency up to the Nyquist limit of the device. Indicate the input exposure used, and the effects of exposure on DQE.

b. MTF or CTF of the device: Provide a plot of the Modulation or Contrast Transfer function of the device. Indicate the device settings and input dose level used to obtain the measurement. If the transfer characteristic varies with any other function indicate how and provide the maximum and minimum transfer functions that the device provides when used with typical clinical exposures.

c. Aliasing: Quantify the effects aliasing has on the DQE and Modulation Transfer Function (MTF) of the device. If aliasing is evidenced from the pre-sampled MTF, quantitatively describe how it affects the resulting image. If there are no aliasing effects from the device indicate why.

d. Transfer Characteristic (Dynamic Range): Provide a plot of the output signal level as a function of input dose level for a specified x-ray spectrum. The spectrum may be defined in terms of kVp and beam half value layer. Plot so that any nonlinearities are clearly shown.

e. Residual signal level from prior exposures short term and long term: Describe, quantitatively where possible, any device characteristics (often due to electron or hole trapping) that cause the device to include in the output, signal components attributable to one or more prior exposures. Indicate the relative amplitude and decay characteristics of such signals.

f. Sensitivity Fatigue: Provide data or a plot of any change in detection sensitivity as a function of time after the device is "ready" for the next exposure. Also indicate any other changes such as reduction in dynamic range that take place after the device is "ready."

g. Spectral Sensitivity variations across the normal radiographic exposure range: Provide a plot of the spectral sensitivity of the device from 30 to 150 kVp in 10 kVp steps. Indicate the beam hardness (half value layer thickness) used.

h. Any means provided to expose and/or readout subsections (partial areas) of the full SSXID: Describe, if this is a characteristic of the device, how it can be under scanned so that only a portion of the total detector matrix is utilized.

j. Alignment and Collimation: Describe how x-ray beam alignment and collimation to the "active" area of the device will be achieved to meet the requirements of 21CFR1020.31.

k. Defect Characteristics: Describe the allowable types and quantity of defects, and any methods of compensation or blanking that are utilized to compensate for allowable maximum output, minimum output or otherwise inoperative cells.

l. Image Erasure/Fading: Provide a plot of the decay characteristic as a function of time and temperature. Also describe any impact on signal retention as a function of the number of erasures and/or exposures the device has experienced.

m. Recovery Time: Provide a measure of the time required for a device to recover from an exposure-readout cycle and be ready for the next exposure to begin.

4. Exposure Characteristics

a. Dose Requirements and any reciprocity changes: Provide quantitative measurements of the device input dose required to generate an image equivalent to that provided by a cleared predicate device using the same dose. Also indicate any changes in this characteristic that will occur with time and/or cumulative radiation exposure.

b. Stability of device characteristics with time (total integrated exposure): In addition to exposure requirement changes, indicate any other characteristics of the device that change with time and/or total integrated exposure.

c. Uniformity of device characteristics (large and small area): Describe any nonuniformity characteristics of the device that may cause large or small area changes such as shading.

d. Reuse Rate: Indicate the maximum number of images that can be generated per unit time. If limited by other than the device itself, describe.

5. Safety Features

a. Indicate what means are provided to ensure the SSXI is ready to accept, process and store the signal resulting from an x-ray input before an exposure is permitted.

b. Describe the means provided to couple with the beam limiting device to ensure that the entire exposed area is being detected and is capable of being read-out.

6. Test Results

a. Provide samples of test pattern images that show the ability of the device to provide images equivalent to those of a predicate device(s). Each image should include the x-ray factors used and the set-up parameters of the device. The test patterns must be clearly identified and all characteristics indicated (e.g. lp/mm for each bar group). The geometry of the test set-up must be indicated as well as the focal spot size of the x-ray source. The images should be on film recorded from the output. If processing is used to demonstrate capabilities such as dynamic range the details of the processing shall be provided.

b. Provide sample measurements of the characteristics described in 3 and 4 above.

VII. Clinical Considerations In addition to the nonclinical information described above, the following clinical information specific to SSXI's should also be included if the predicate is either film or an image intensifier. If the predicate is another SSXI, clinical data may not be required unless there are technological and /or functional differences between the new and predicate SSXI's.

A. For Fluoroscopic Applications

1. Conduct and report the results of a study of 30 or more clinical image pairs that show the ability of the device to provide images of equivalent diagnostic capability to those of a cleared predicate device(s). These images may be either on VHS video tape or film generated from the video signal. Each image should be supported with the x-ray factors and set-up used as well as the operating parameters of the device and any processing performed. Classical hypothesis testing or Bayesian methods may be used to demonstrate equivalence.

2. Representative sets of sample images (device and predicate) should be submitted for each anatomical region (and/or study) that is indicated for the device.

3. Provide any other clinically significant findings that are discovered in the process of using the device.

B. For Radiographic Applications

1. Conduct and report the results of a study of 30 or more clinical image pairs that show the ability of the device to provide images of equivalent diagnostic capability to those of a cleared predicate device(s). These film images may be either positive or negative. Each image should be supported with the x-ray factors and set-up used as well as the operating parameters of the device and any processing performed. Classical hypothesis testing or Bayesian methods may be used to demonstrate equivalence.

2. It is suggested that representative sets of sample images (device and predicate) be submit each anatomical region (and/or study) that is indicated for the device.

3. Provide any other clinically significant findings that are discovered in the process of using the device.

VIII. Labeling: A premarket submission for an SSXI device should contain information on device labeling. The information provided should include:

A. Indication(s) for Use: A general description of the disease(s) or condition(s) that the device will be used to help diagnose and the patient population for which the device is intended.

Examples:

The _____ is indicated for use in generating real time fluoroscopic images in patients where medically indicated.

The _____is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

B. Promotional Materials: All brochures and advertising copy that have been prepared to promote the use and sale of the device.

C. Instructions for Installation, Check-Out and Use

1. User's Manual: A description of the methods for selection of the x-ray technique factors,image processing algorithms, and display settings (e.g. window width, window position, gray scale transfer characteristic, etc.) for the generation of the displayed image. All cautions, warnings, and contraindications associated with the use of the device. State the fill factor achieved by the device and indicate over what exposure range (and frame rates for fluoroscopic devices) the device's operation is not quantum limited.

2. Device Life: Indicate the total expected life, i.e. when the device should be replaced. This may be in terms defined by the manufacturer such as calendar time or total integrated dose. Instructions for the physical replacement should also be included.

3. Ancillary Requirements: This information should include instructions on which particular display device(s) is appropriate and the method of using such display device(s) to achieve the intended use(s). A description, if applicable, of any instructions needed to obtain optimum images from either hard-copy (laser camera) or soft-copy (CRT) device(s) that will display the SSXI generated image.

D. Training Materials: To address the issue of how to account for the "learning curve" effect in the clinical utilization of an SSXI device, it is the FDA's position that an approach to moving up the "learning curve" may be demonstrated by the use of a set of comprehensive training materials. A complete description of all training materials to be used by the manufacturer should be provided as part of the submission.

E. Documentation: In considering the total content of the labeling for this category of device, it is the FDA's position that users should be provided with objective documentation of imaging performance from the manufacturers. Users can then employ this information in their evaluation of the importance of any tradeoffs between different characteristics of imaging performance. The documentation should include the data described in response to the Clinical and Nonclinical Considerations sections of this guidance encompassing: sensitometric response characteristics, spatial resolution properties, DQE, dynamic range and the display means utilized, the results of phantom image tests, and the required patient input doses.

IX. Quality Assurance Program A submission should contain a complete description of the quality assurance program for the entire SSXI acquisition and display system. The description should include the following information:

A. A list of the parameters to be monitored and the frequency of monitoring.

B. A description of the standards, quality criteria, or limits of acceptance that are in place for each of the monitored parameters.

C. A description of the procedures to be used for monitoring each parameter.

D. A list of the records, with sample forms (if applicable) that the manufacturer will maintain for the QA program.

E. A description of all training materials to be provided for performing, recording, and monitoring QA tests.